Virginia Department of Health
Division of Disease Prevention - Tuberculosis
Guidelines for Determination of Completion of Treatment

In February 2003, the American Thoracic Society (ATS), Infectious Diseases Society of America (ISDA) and the Centers for Disease Control and Prevention (CDC) published new treatment recommendations and guidelines for the treatment of active tuberculosis disease. The Division of Disease Prevention – Tuberculosis Program (DDP-TB) concurs with the treatment recommendations and guidelines of the ATS, ISDA and CDC. The full text of this document can be found in the "Treatment of Tuberculosis." MMWR 2003;52(No. RR-11).

This document provided new guidance on calculating adequate treatment for those under care for active tuberculosis. Completion of therapy is now based not on months and weeks of therapy, but on the actual number of doses ingested within specified time frames. In order to assist local districts and case managers in determine if patients have completed an adequate course of therapy, DDP-TB has prepared the following guidelines.

1. The selection of an appropriate individual regimen is based on a number of individual patient characteristics, a discussion of which can be found the treatment statement.

2. Definitions
    a. D.O.T. – Directly Observed Therapy. Every dose of medication is observed by health care worker.
    b. Self – All doses are self-administered, or less than ½ observed by health care worker.
    c. DOT/self – More than ½ of doses are observed by health care worker, with the remainder of the doses self-administered.
3. For patients on self-administered therapy, only daily 7 day per week regimens may be used. All intermittent treatment regimens (i.e. twice weekly or thrice weekly require DOT. Self administration is not permitted with intermittent regimens.

4. Ideally all treatment regimens should be completed within the specified timeframes, i.e. 6-month regimens within 6 months and 9-month regimens within 9 months. In situations where there are treatment interruptions due to drug intolerance or non-adherence, the following guidelines should be used. If the patient fails to complete treatment within the extended timeframes, treatment should be restarted from the beginning. **Above all, it is critical to reach the required number of doses within the maximum acceptable timeframe.** All 6-month regimens should be completed within 9 months with the 2-month initial phase completed within 3 months and the 4-month continuation phase completed within the final 6 months. All 9-month regimens should be completed within 12

months with the 2-month initial phase completed within 3 months and the 7-month continuation phase completed within the remaining 9 months.

5. The number of doses required for completion varies with the regimen selected.

6. DDP-TB concurs with the ATS/CDC/ISDA position of DOT as the standard of care for all individuals on treatment for active TB in Virginia. If limited resources do not permit universal DOT, patients with the following conditions/circumstances are considered a priority and DOT should be used with rare exceptions.
    a. Smear positive, pulmonary tuberculosis
    b. Treatment failure or relapse
    c. Drug resistance
    d. HIV infection
    e. Previous treatment for TB disease or latent TB infection
    f. Current or prior substance abuse
    g. Psychiatric illness
    h. Memory impairment
    i. Previous nonadherence to therapy
    j. TB in child or adolescent

7. In instances where DOT is not selected by the health department or local provider, documentation of the reason for self-administration should be placed in the chart along with actions taken by the health department, including health director review and approval of treatment plans as mandated by Virginia's TB Control statutes.

8. When DOT is not used, the health department should obtain a written certification of compliance from the physician managing the care. In this statement the physician should certify the number of weeks that the patient received each drug. Activities to monitor adherence such as pill counts, monitoring pharmacy pick-ups etc. are also appropriate to monitor patients for whom DOT is not provided. **The health department is ultimately responsible for assuring that a complete course of treatment has been achieved.**

9. For patients on DOT, DDP-TB encourages the use of the 5day/week regimen for the daily treatment schedule. Regimens with self-administered medications on weekends are discouraged.

10. Regardless of whether medications were provided for self-administration on weekends and holidays, only M-F weekday doses will be counted toward dose counts for completion of therapy.

11. Every dose of medication should be accounted for and documented, whether by DOT or self-administration. For patients on self-administration, acceptable

documentation may include a progress note discussing the patient's self report of compliance or documentation concerning pill counts, pharmacy refill pick-up, etc.

12. In instances when the patient is admitted to a residential facility (i.e. hospital, jail, etc), the district will need to assess the quality of the medication delivery system at that facility to determine if doses provided will count towards to dose counts required for completion of therapy. If these doses are counted towards the completion of therapy totals, copies of medication records should be obtained.

13. For patients on non-standard regimens due to drug resistance or drug intolerance, DDP-TB should be consulted regarding the length of treatment required for adequate completion of therapy. DOT is required for all non-standard treatment regimens.

Doses Required for Completion of Initial Phase of Treatment
(I,R,E,Z regimens only. Not for use for cases on second line drugs)

Regimen	**Days per week**	**Total doses**	**Number of weeks**
Daily	7 days per week	56	8
*Weekday daily	5 days per week	40	8
Two weeks daily, then twice weekly	7 days/week for 2 weeks, then two times per week	14 daily doses, then 12 twice weekly doses (26 total doses)	8
*Two weeks weekday daily, then twice weekly	5 days /week for 2 weeks, then two times per week.	10 weekday daily doses, then 12 twice weekly doses (22 total doses)	8
Thrice weekly	3 times per week	24	8

*DDP-TB recommended option.

Doses Required for Completion of Continuation Phase of Treatment (Use for uncomplicated cases on INH/rifamycin regimens only. Not for use for cases on second line drugs)			
Regimen	**Days per week**	**Total doses**	**Number of weeks**
Daily	7 days per week	126	18
Weekday daily	5 days per week	90	18
*Twice weekly	2 days per week	36	18
#Once weekly (INH/rifapentine regimen only)	1 day per week	18	18
~Thrice weekly	3 days per week	54	18

*DDP-TB recommended option except for patients with HIV infection.
#Once weekly rifapentine regimen for use only with patients who meet selection criteria
~Only intermittent regimen recommended for patients with HIV infection and CD4 counts <100/mm. DDP-TB recommends caution in the use of twice-weekly regimens for any HIV infected patient. Once weekly regimens are contraindicated for patients with HIV infection.

Doses Required for an Extra Three Months of Treatment (Use for any regimen when treated is extended for an additional 3 months)			
Regimen	**Days per week**	**Total doses**	**Number of weeks**
Daily	7 days per week	91	13
Weekday daily	5 days per week	65	13
*Twice weekly	2 days per week	26	13
#Once weekly (INH/rifapentine regimen only)	1 day per week	13	13
~Thrice weekly	3 days per week	39	13